AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all previous versions and listings of claims in this application:

1. (Currently Amended) A method of preparing a sustained release formulation of a peptide or peptidomimetic, which comprises associating the peptide or peptidomimetic with a counter-ion of a strong proton donor in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension of the peptide suspended at a concentration of at least 25 mg/mL without formation of a gel, such that, when administered to a subject, the peptide is released in vivo over a period of at least two weeks, wherein the peptide is Ac—D—Nal—DCpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2.

2. (Original) The method of claim 1, wherein the counter-ion is a trifluoromethanesulfonic acid, benzenesulfonic acid, trifluoroacetic acid or sulfuric acid.

3. (Cancelled)

4. (Cancelled)

5. (Cancelled)

6. (Currently Amended) ~~The method of claim 4,~~A method of preparing a sustained release formulation of a GnRH antagonist, which comprises associating the GnRH antagonist with a counter-ion of a strong proton donor in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension of the GnRH antagonist suspended at a concentration of at least 25 mg/mL without formation of a gel, such that, when administered to a subject, the GnRH antagonist is released in vivo over a period of at least two weeks, wherein the GnRH antagonist is Azaline B, Abarelix, Antide, Ganirelix, Cetrorelix, or FE200486 and is in the form of an alkylsulfonate, arylsulfonate, trifluoroacetate or sulfate salt.

7. (Currently Amended) ~~The method of claim 1~~, A method of preparing

a sustained release formulation of a peptide, which comprises associating the peptide with a counter-ion of a strong proton donor in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension of the peptide suspended at a concentration of at least 25 mg/mL without formation of a gel, such that, when administered to a subject, the peptide is released in vivo over a period of at least two weeks, wherein the peptide is a somatostatin analogue.

8. (Currently Amended) The method of ~~claim 1~~ claim 7, wherein the somatostatin analogue is Vapreotide, Octreotide, Lanreotide, or SOM 230.

9. (Previously Presented) The method of claim 1, wherein the peptide or peptidomimetic forms a salt with the counter-ion, and the salt is suspended in the aqueous medium at a concentration of at least 25 mg/mL.

10. (Previously Presented) The method of claim 9, wherein the aqueous suspension is injected parenterally into a mammal or human subject to obtain a sustained release of the peptide or peptidomimetic over at least one month.

11. (Previously Presented) The method of claim 9, wherein the amount of peptide or peptidomimetic in the suspension to be injected ranges from about 0.1 to 5 mg per kg body weight of the mammal or human subject.

12. (Currently Amended) A fluid, milky microcrystalline aqueous suspension of a peptide or peptidomimetic and a counter-ion of a strong proton donor in water, wherein the peptide or peptidomimetic and counter-ion are present in amounts and at a molar ratio sufficient to form the suspension of the peptide at a concentration of at least 25 mg/mL upon mixing without formation of a gel, wherein the peptide is Ac—D—Nal—DCpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2.

13. (Original) The suspension of claim 12, wherein the counter-ion is trifluoromethanesulfonic acid , benzenesulfonic acid, trifluoroacetic acid, or sulfuric acid.

14. (Cancelled)

15. (Cancelled)

16. (Cancelled)

17. (Currently Amended) ~~The suspension of claim 14~~, A fluid, milky microcrystalline aqueous suspension of a GnRH antagonist and a counter-ion of a strong proton donor in water, wherein the GnRH antagonist and counter-ion are present in amounts and at a molar ratio sufficient to form the suspension of the GnRH antagonist at a concentration of at least 25 mg/mL upon mixing without formation of a gel, wherein the GnRH antagonist is Azaline B, Abarelix, Antide, Ganirelix, Cetrorelix, or FE200486 and is in the form of an alkylsulfonate, arylsulfonate, trifluoroacetate or sulfate salt.

18. (Currently Amended) ~~The suspension of claim 12~~,A fluid, milky microcrystalline aqueous suspension of a peptide and a counter-ion of a strong proton donor in water, wherein the peptide and counter-ion are present in amounts and at a molar ratio sufficient to form the suspension of the peptide at a concentration of at least 25 mg/mL upon mixing without formation of a gel, wherein the peptide is a somatostatin analogue.

19. (Previously Presented) The suspension of claim 18, wherein the somatostatin analogue is Vapreotide, Octreotide, Lanreotide or SOM 230.

20. (Previously Presented) The suspension of claim 12, wherein the peptide or peptidomimetic forms a salt with the counter-ion, and the salt is suspended in the aqueous medium at a concentration of equal to or higher than 25 mg/mL.

21. (Previously Presented) The suspension of claim 12, wherein the aqueous suspension contains an isotonic agent.

22. (Previously Presented) The suspension of claim 21, wherein the isotonic agent is mannitol.

23. (Previously Presented) The suspension of claim 12, which further comprises a pharmaceutically acceptable excipient.

24. (Previously Presented) The suspension of claim 23, wherein the amount of peptide or peptidomimetic ranges from about 0.1 to 5 mg per kg body weight of a mammal or human to which the suspension is to be administered.

25. (Previously Presented) The suspension of claim 12, wherein the peptide is at least partially in the form of microcrystals having a particle size of between about 1 and 150 μm.

26. (Previously Presented) A lyophilized composition comprising a dried suspension of claim 12.

27. (Previously Presented) A method of making the lyophilized composition of claim 26 which comprises associating the peptide or peptidomimetic with a counter-ion of a strong proton donor in an amount and at a molar ratio that are sufficient to provide the suspension without formation of a gel, and lyophilizing the suspension to obtain the composition.

28. (Previously Presented) A method of preparing a fluid, milky microcrystalline aqueous suspension of a peptide or peptidomimetic which comprises adding water or a buffer solution to the lyophilized composition of claim 26 with mixing to obtain the suspension.

29. (Currently Amended) A method of preparing the suspension of claim 12, ~~a fluid, milky microcrystalline aqueous suspension of a peptide or peptidomimetic~~ which comprises associating the peptide or peptidomimetic with a counter-ion of a strong proton donor in an amount and at a molar ratio with the peptide that are sufficient to provide a fluid, milky microcrystalline aqueous suspension of the peptide or peptidomimetic at a concentration of at least 25 mg/mL without formation of a gel; lyophilizing the suspension to form a lyophilized composition; and adding water or a buffer solution to the lyophilized composition with mixing to obtain the suspension.

30-31. (Cancelled)

32. (Previously Presented) A fluid, milky microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·trifluoroacetate.

33. (Previously Presented) The suspension of claim 32, which provides, when administered to a subject, a sustained release of peptide in vivo.

34. (Previously Presented) The suspension of claim 33, wherein the sustained release is over a period of two weeks.

35. (Previously Presented) The suspension of claim 32, wherein Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·trifluoroacetate is suspended in an aqueous medium at a concentration of equal to or greater than 25 mg/mL.

36. (Previously Presented) The suspension of claim 32, further comprising an isotonic agent.

37. (Previously Presented) The suspension of claim 36, wherein the isotonic agent is mannitol.

38. (Previously Presented) The suspension of claim 32, further comprising a pharmaceutically acceptable excipient.

39. (Previously Presented) The suspension of claim 32, wherein microcrystals are in the form of needles having a particle size of between 1 and 150 μm.

40. (Previously Presented) A method of preparing the suspension of claim 32 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 with trifluoroacetate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without formation of a gel.

41. (Previously Presented) A method of preparing a lyophilized composition comprising Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·trifluoroacetate comprising, lyophilizing the suspension of claim 32.

42. (Previously Presented) A lyophilized composition comprising a dried suspension obtained by the method of claim 41.

43. (Previously Presented) A method of preparing a microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·trifluoroacetate comprising, adding water or buffer with mixing to the lyophilized composition of claim 42.

44. (Previously Presented) A method of preparing the suspension of claim 32 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 with trifluoroacetate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without formation of a gel; lyophilizing to form a lyophilized composition; and adding water or buffer with mixing.

45. (Previously Presented) A fluid, milky microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·sulfate.

46. (Previously Presented) The suspension of claim 45, which provides, when administered to a subject, a sustained release of peptide in vivo.

47. (Previously Presented) The suspension of claim 46, wherein the sustained release is over a period of two weeks.

48. (Previously Presented) The suspension of claim 45, wherein the Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·sulfate is suspended in an aqueous medium at a concentration of equal to or greater than 25 mg/mL.

49. (Previously Presented) The suspension of claim 45, further comprising an isotonic agent.

50. (Previously Presented) The suspension of claim 49, wherein the isotonic agent is mannitol.

51. (Previously Presented) The suspension of claim 45, further comprising a pharmaceutically acceptable excipient.

52. (Previously Presented) The suspension of claim 45, wherein microcrystals are in the form of needles having a particle size of between 1 and 150 μm.

53. (Previously Presented) A method of preparing the suspension of claim 45 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 with sulfate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without formation of a gel.

54. (Previously Presented) A method of preparing a lyophilized composition comprising Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·sulfate comprising, lyophilizing the suspension of claim 45.

55. (Previously Presented) A lyophilized composition comprising a dried suspension obtained by the method of claim 54.

56. (Previously Presented) A method of preparing a microcrystalline aqueous suspension of Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2·sulfate comprising, adding water or buffer with mixing to the lyophilized composition of claim 55.

57. (Previously Presented) A method of preparing the suspension of claim 45 comprising, associating Ac—D—Nal—D—Cpa—D—Pal—Ser—Tyr—D—Hci—Leu—Ilys—Pro—D—Ala—NH_2 with the sulfate counter-ion in an amount and at a molar ratio that are sufficient to provide a fluid, milky microcrystalline aqueous suspension without

formation of a gel; lyophilizing to form a lyophilized composition; and adding water or buffer with mixing.

58. (New) The method of claim 7, wherein the counter-ion is a trifluoromethanesulfonic acid, benzenesulfonic acid, trifluoroacetic acid, or sulfuric acid.

59. (New) The suspension of claim 18, wherein the counter-ion is trifluoromethanesulfonic acid, benzenesulfonic acid, trifluoroacetic acid, or sulfuric acid.